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Docket No. 0575/59472-A-PCT-US/JPW/FHB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE RECEIVED

Applicants

David Stern et al.

FEB 0 5 2003

Serial No.

10/049,893

TECH CENTER 1600/290

Filed

July 22, 2002

For

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METHODS OF INHIBITING BINDING OF BETA-SHEET

FIBRIL TO RAGE AND CONSEQUENCES THEREOF

1185 Avenue of the Americas New York, New York 10036 January 27, 2003

Commissioner for Patents and Trademarks Washington, D.C. 20231-9999

Sir:

TRANSMITTAL OF VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS UNDER 37 C.F.R. §1.9(f) AND §1.27

The Trustees of Columbia University In the City of New York, the assignee, submits herewith a Verified Statement (Declaration) Claiming Small Entity Status Under 37 C.F.R. §1.9(f) and §1.27(c) as Exhibit A. This Verified Statement is signed by Adnan M.M. Mjalli, Ph.D., the President and C.E.O. of TransTech Pharma.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents and Trademarks Washington, D.C. 20231-9999

TRA Ot 1/2

Reg. No. 28,678

1/3/11/0

John P White Registration No. 28,678 Attorneys for Applicants Cooper & Dunham LLP 1185 Avenue of the Americas New York, New York 10036

(212) 278-0400

Applicant or Patentee: <u>David Stern</u> , et al.	Attorney's
Serial or Patent No.: 10/049,893 Filed or Issued: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	Docket No.: 59472-A-PCT-U
Title of Invention or Patent: METHODS OF INHIBITING BINDI	NG OF BETA-SHEET FIRRIL
TO RAGE AND CONSEQUENCES TH	
	RECEIVED
FEB 0 3 2003 W VERIFIED STATEMENT (DECLARATION) CLAIM	
SMALL ENTITY STATUS UNDER 37 C.F.R. \$1.9	
AND \$1.27(c) - SMALL BUSINESS CONCERN	N
RADEMARK	TECH CENTER 1600/2900
I hereby declare that I am:	
the owner of the small business concern identifie	d below.
an official of the small business concern empowered concern identified below:	to act on behalf of the
Name of Concern: TransTech Pharma	
Address of Concern: 4170 Mendenhall Oaks Parkway	
High Point, North Carolina 27265	
I hereby declare that the above identified small business of small business concern as defined in 13 C.F.R. §121.3-18, re §1.9(d), for purposes of paying reduced fees under 35 U.S.C. that the number of employees of the concern, including those of not exceed five hundred (500) persons. For purposes of this verifical year, of the persons employed by the business compartatime, or temporary basis during each pay period of concerns are affiliates of each other when, either directly concern controls or has power to control the other, or a temporary basis of the other, or a temporary basis of the pay period of concerns are affiliates of each other when, either directly concern controls or has power to control the other, or a temporary basis of the other, or a temporary basis of the pay period of concern controls or has power to control the other, or a temporary basis of the pay period of the other, or a temporary basis of the pay period of concern controls or has power to control the other, or a temporary declare that rights under contract or law have been with the small business concern identified above with regentitled METHODS OF INHIBITING BINDING OF BETA-SHEET FIBRIL AND CONSIDERATIONS OF THE PROOF THE PROOF OF THE PROOF O	sproduced in 37 C.F.R. \$41(a) and \$41(b), in of its affiliates, does erified statement, the mber, over the previous ocern on a full-time, the fiscal year, and ly or indirectly, on third party or parties conveyed to and remain and to the invention
the specification filed herewith application serial no. 10/049,893 filed Kannannannannannannannannannannannannann	XXXXX July 22, 2002
If the rights held by the above identified small business conceach individual, concern or organization having rights to the below and no rights to the invention are held by any peinventor, who could not qualify as an independent inventor under any concern which could not qualify as a small busines C.F.R. \$1.9(d)* or as a nonprofit organization under 37 C.F.	e invention is listed rson, other than the er 37 C.F.R. \$1.9(c)*, ss concern under 37
Name: The Trustees of Columbia University in the City of No	ew York
Address: 110 Low Memorial Library, Amsterdam and 120th Street	
New York, New York 10027 Individual Small Business Concern X Nonpro	Fit Organization
	TIC Organizacion

anome: Separate verified statements are required for each named person, concern, or organization having rights to the invention averring to their status as small entities. 37 C.F.R. §1.27.

- (c) An independent inventor as used in this chapter means any inventor who (1) has not assigned, granted, conveyed, or licensed, and (2) is under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not likewise be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section.
- (d) A small business concern as used in this chapter means any business concern a defined by the Small Business Administration in 13 C.F.R. §121.3-18, published of September 30, 1982 at 47 FR 43273. For the convenience of the users of these regulations, that definition states:
- \$121.3-18 Definition of small business for paying reduced patent fees under Title 35, U.S. Code.
- (a) Pursuant to Pub. L. 97-247, a small business concern for purposes of paying reduced fees under 35 U.S. Code 41(a) and (b) to the Patent and Trademark Office means any business concern (1) whose number of employees, including those of its affiliates, does not exceed 500 persons and (2) which has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit For the purpose of this section concerns are. organization under this section. affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. The number of employees of the business concern is the average over the fiscal year of the the persons employed during each of the pay periods of the fiscal year. Employees are those persons employed on a full-time, part-time or temporary basis during the previous fiscal year of the concern.
- (b) If the Patent and Trademark Office determines that a concern is not eligible as a small business concern within this section, the concern shall have a right to appeal that determination to the Small Business Administration. The Patent and Trademark Office shall transmit its written decision and the pertinent size determination fil to the SBA in the event of such adverse determination and size appeal. Such appeals by concerns should be submitted to the SBA at 1441 L Street, NW., Washington, D.C. 20416 (Attention: SBA Office of General Counsel). The appeal should state the basis upon which it is claimed that the Patent and Trademark Office initial size determination on the concern was in error; and the facts and arguments supporting the concern's claimed status as a small business concern under this section.
- (e) A nonprofit organization as used in this chapter means (1) a university or other institution of higher education located in any country; (2) an organization of th type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)(3)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)); (3) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 U.S.C. 201(i)); or (4) any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under paragraphs (e)(2) or (3) of this section if it were located in this country.

Small Entity/Small Business Concern Page -2-

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b)*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing:	Adnan M.M. Mjalli, Ph.D.	
Title In Organization:	President and CEO	_
-ddress:	4170 Mendenhall Oaks Parkway	
	High Point, NC 27265 C	
Signature:	1. MANUE	_
Date Of Signature:	House for for	
	2/13/01	

37 C.F.R. §1.28(b)

(b) Once status as a small entity has been established in an application or patent, fees as a small entity may thereafter be paid in that application or patent without regard to a change in status until the issue fee is due or any maintenance fee is due. Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate pursuant to \$1.9 of this part. The notification of change in status may be signed by the applicant, any person authorized to sign on behalf of the assignee, or an attorney or agent of record or acting in a representative capacity pursuant to \$1.34(a) of this part.



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Serial No.

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No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed

Commissioner for Patents and Trademarks Washington, D.C. 20231-9999

John P. White

127/03

Date

John P. White Registration No. 28,678 Attorneys for Applicants Cooper & Dunham LLP 1185 Avenue of the Americas New York, New York 10036 (212) 278-0400

Applicant or Patentee: David Stern, et al.	Attorney's
Serial or Patent No.: 10/049,893	Docket No 59472-A-PCT-US
Filed or Issued: KXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
Title of Invention or Patent: METHODS OF INHIBITING BINDING	OF BETA-SHEET FIBRIL
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TO RAGE AND CONSEQUENCES THERE	RECEIVED
VERIFIED STATEMENT (DECLARATION) CLAIMIN SMALL ENTITY STATUS UNDER 37 C.F.R. \$1.90	FEB 0 5 2003
SMALL ENTITY STATUS UNDER 37 C.F.R. \$1.90	(f)
AND \$1 27(4) - NONE POPIT OF CANTATION	
AND \$1.27(d) - NONFROFII ORGANIZATION	TECH CENTER 1600/2900
TRADE TO ST. 27(d) - NONPROFIT ORGANIZATION	
I UGIGDA deciste cuer i em en otificial embowered co ecc ou o	enair or the nonprofit
organization identified below:	
Name of Organization: The Trustees of Columbia University	<u>in the City of New York</u>
Address of Organization: 110 Low Memorial Library, Amsterdar	m and 120th Street
New York, New York 10027	
TYPE OF ORGANIZATION:	
· X UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION	11 0 0 66601(-)
TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26	U.S.C. 35501(a) and
501(c)(3)	
NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF	F STATE OF THE UNITED
STATES OF AMERICA	·
NAME OF STATE:	
CITATION OF STATUTE:	
WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SE	
\$\$501(a) and 501(c)(3) IF LOCATED IN THE UNITED STATE	S OF AMERICA
WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL 1	UNDER STATUTE OF STATE
OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNI	ITED STATES OF AMERICA
NAME OF STATE:	
CITATION OF STATUTE:	
I hereby declare that the nonprofit organization identified	above qualifies as a
nonprofit organization as defined in 37 C.F.R. \$1.9(e)* for	or purposes of paving
reduced fees under 35 U.S.C. §41(a) and 41(b), with regard to	the invention entitl d
METHODS OF INHIBITNG BINDING OF BETA-SHEET FIBRIL TO RAGE AND	D CONSEQUENCES THEREOF
METHODS OF IMITEDIAN DINETHO OF PARTY BRIDGE TO THE TANK	
by inventor(s) David Stern, Shi Du Yan, and Ann Marie Schmid	E
by Inventor(s) Bavia otern, but be ital, and italia sommes.	
described in:	
the specification filed herewith	
	7786687 T. 1 22 2002
x application serial no. 10/049,893 filed XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	122002 July 22, 2002
patent noissued	· · · · · · · · · · · · · · · · · · ·
I hereby declare that rights under contract or law have been o	conveyed to and remain
with the nonprofit organization with regard to the above iden	itified invention.
·	
If the rights held by the nonprofit organization are not exclu	sive each individual,
concern, or organization known to have rights to the invention	n is listed below and
no rights to the invention are held by any person, other than t	he inventor, who could
not qualify as a small business concern under 37 C.F.R. \$1.	.9(d)* or a nonprofit
organization under 37 C.F.R. 1.9(e)*	-
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NOTE: Separate verified statements are required from each	n person, concern, or
NOTE: Separate verified statements are required from each reganization having rights to the invention averring to the	heir status as small
reanization having 1+6mts to the invention averting to the	ICAL UNGCED NO DINGAL
ntities. 37 C.F.R. §1.27.	
m n 1 Di	
ame: TransTech Pharma	

37 C.F.R. §§1.9(d), 1.9(e)

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Small Entity/Nonprofit Page -2-

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b)*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Title In Organization.	Michael J. Cleare, Ph.D. Executive Director, Columbia Innovation Enterprise Engineering Terrace - Suite 363 Anglerdam and 120th Street, New York, NY 10027
Signature:	1 2/14/02

37 C.F.R. \$1.28(b)

(b) Once status as a small entity has been established in an application or patent, fees as a small entity may thereafter be paid in that application or patent without regard to a change in status until the issue fee is due or any maintenance fee is due. Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate pursuant to §1.9 of this part. The notification of change in status may be signed by the applicant, any person authorized to sign on behalf of the assignee, or an attorney or agent of record or acting in a representative capacity pursuant to §1.34(a) of this part.